BFGoodrich

8(e)

The BFGoodrich Company
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April 8, 1996

Document Control Officer
Chemical Information Division
Office of Toxic Substances
Room E-108
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Re: Notice of Substantial Risk Under TSCA Section 8(e)

Dear Sir/Madam:

The B.F.Goodrich Company (BFG) submits this supplemental information in accordance with Section 8(e) of the Toxic Substances Control Act (TSCA) and EPA's numerous interpretive statements. This submission does not contain confidential business information.

We are notifying the EPA of information from an occupational health survey of our workers who were involved with the manufacture of high molecular weight, polyacrylate products at our Calvert City, Kentucky plant. Although we are making this submission to ensure compliance with the latest expressed indications of the EPA for reporting such information, the EPA should note that these results are not definitive and do not provide evidence of irreversible effects from occupational exposure to these products.

Background

In 1983 BFG conducted an occupational health survey of its polyacrylate workers at Calvert City, Kentucky to support a PMN and to address the EPA's concerns about the results of *in vitro* and *in vivo* mouse macrophage studies that had been submitted by another company under TSCA 8e. Our survey compared the incidence of abnormal pulmonary function test results and chest x-rays in our polyacrylate workers with that of non-polyacrylate workers at the plant. A comparison of the results indicated that the incidence of lung abnormalities in the polyacrylate workers was comparable to the control group.

More recently a second study of our polyacrylate workers at Calvert City was conducted to address questions raised by various lung toxicity and mechanistic studies on a high molecular weight superabsorbant polyacrylate polymer that were submitted under TSCA 8e. Because adequate quantitative exposure data was not available, weighted exposures were determined for each worker based on a relative exposure ranking of jobs and with number of years employed in each job. Based on these relative weighted exposure estimates, the workers were grouped according to low, medium ,or high exposure. Lung cancer morbidity and mortality, pulmonary function test data, chest x-ray findings, employee demographics, smoking histories, and other pertinent data were obtained from our Occupational Health Surveillance System (OHSS). These data then were assessed across exposure groups.

Significance/Assessment of the Data

A review and analysis of the data from the OHSS revealed that there were no lung cancers cases in this population and that there was no increase in chest x-ray abnormalities associated with exposure. However, there was a statistically significant trend for deceased lung capacity associated with increased weighted exposure.

Because these findings are preliminary, we are continuing our review and assessment of the data to fully understand the

significance of these findings. Furthermore, we are continuing our efforts to minimize worker exposures by modifying work practices and engineering controls and to communicate new findings to our workers and customers.

If you have any questions regarding this submission, please contact Dr. Robert K. Hinderer at (216) 447-5181.

Sincerely,

THE BFGOODRICH COMPANY

Carl A. Mattia/RKH

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CAM/rh

D R A F T

OCCUPATIONAL HEALTH SURVEY OF THE RESPIRATORY STATUS OF POLYACRYLATE WORKERS

by

Richard Lewis, M.D., MPH

April 8, 1996

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Background

Over the past ten years, a number of animal studies have suggested that inhalation of high levels of respirable polyacrylate dust may have adverse effects on lung tissue. In 1982 *in vivo* studies in rats using varying exposure regimens for 13 weeks found evidence that a partial aluminum potassium salt of polyacrylic acid causes damage to pulmonary macrophage and other lung tissue.[1] *In vitro studies* also found that a partial sodium salt of polyacrylic acid, a partial salt of an acrylic acid-starch graft, and polyacrylic acid were toxic to mouse macrophage cells[1]. Subsequent two week and three month rat inhalation studies with another polyacrylic polymer found evidence of inflammation in the lower lungs which persisted during the recovery period[2]. Although these subchronic studies did not find any serious lung effects, a two year rat inhalation study of high molecular weight polyacrylate salt found a range of non-neoplastic inflammatory and proliferative lesions in the middle exposure levels and neoplastic lesions (bronchiolar/ alveolar adenomas and adenocarcinomas) at the highest exposure[3] .

In contrast to the animal data, there has been no evidence of adverse lung effects in humans related to polyacrylate exposure. The BFGoodrich Company found no evidence of lung function or chest x-ray abnormalities in an occupational health survey of employees involved in the manufacture of polyacrylate products at Calvert City, Kentucky[4] . Rohm and Haas also reported no evidence of differences in chest x-rays and lung function testing in exposed and non-exposed workers employed from 1966 - 83[5]. However, because of the more recent animal findings, the BFGoodrich initiated a follow-up survey of the health of Calvert City employees who work with these products.

Methods

All employees who had potential exposure to polyacrylate dust at the Calvert City, Kentucky facility for over one year were identified from plant records. Job classifications and work histories were assembled by facility personnel. Lung function measurements, chest x-ray results, smoking history and vital status were determined using data collected in the BFGoodrich medical surveillance system.

The evaluation consisted of a cross-sectional analysis of the lung function measurements and chest x-ray results of the study population. While most participants had multiple studies conducted at the facility, after a review of the available data only the most recent tests were used in this survey. All pulmonary function data was obtained from the BFGoodrich Occupational Health Surveillance System. Most of the participants had lung function testing conducted in the 1990's. Pulmonary function results were analyzed using standard predicted equations (Knudson, 1987). To adjust for the effects of age, sex and race the percent predicted values for the Forced Vital Capacity (FVC%), Forced Expiratory Volume in one Second (FEV_1%) and the FEV_1/FVC ratio were used in the analysis. Tests were also classified as being normal, restrictive (FVC% < 80%, normal ratio), or obstructive (FEV_1% < 80% and FVC% $\geq$ 80 predicted, or Ratio < 70%). For employees whose chest x-rays were classified as abnormal, hard copy reports of the x-ray interpretations were obtained and reviewed. These were re-classified as abnormal if there was evidence of diffuse or localized pulmonary fibrosis.

A relative weighted exposure (RWE) for each employee was determined and reviewed by human resource, health and industrial hygiene staff using an "exposure weighting factor (EWF)" for each job and the employees work history. The EWF's (**Table 1**) were based on the best estimates of the relative intensity of exposure of each job. The RWE was obtained for each

employee by multiplying the EWF by the years worked in each job. The RWE's ranged from 5 to 1,355. The population was divided into Low, Medium, and High exposure groups by ordering the employees by RWE, visually inspecting the distribution and using "best" groupings.

TABLE 1. Exposure weighting factors (EWF) for workers exposed to polyacrylate

Job	Exposure Weighting Factor (EWF)
Packer	50
Dryer	40
Maintenance	20
Foreman/Supervisors Operators/Lab Warehouse Instrument technicians Engineers Office/administration	5

Results

The characteristics of the study group are listed in **Table 2**. There were 164 employees identified for the assessment. The majority (93%) were men. The average age at the time of the review was 51.5 years and the participants had worked at the facility for an average of 20.7 years. Sixty-two percent of the participants were still working at the facility. Forty five (27%) were retired, with the remainder being transferred or terminated. The smoking status of the study group showed that 26% were current smokers. Forty percent had quit smoking and 34% reported never smoking. At the time of the data collection, none of the participants had been identified as having lung cancer and the focus of the survey was directed at evaluation of possible respiratory effects.

TABLE 2. Demographics characteristics of workers exposed to polyacrylate

DEMOGRAPHICS	
Eligible Employees	164
Men Women	153 (93 %) 11 (7%)
Average age (range)	51.5 yrs (23 - 72)
Average hire age (range)	28.4 yrs (20 -57)
Average years at site (range)	20.7 yrs (1 - 39)
Employment Status	
Active Retired Terminated Transfer	101 (62%) 45 (27%) 8 (5%) 10 (6%)
Smoking Status	
Current Former Never	43 (26%) 65 (40%) 56 (34%)

The characteristics of the three groups are summarized in **Table 3**. The high and medium groups were slightly older than the low exposure group. There were also more current smokers in the high group, with more persons in the low group reporting never smoking. The age and smoking differences of the exposure sub-populations were not statistically significant.

Table 4 lists the results of lung function testing. The means of the percent predicted values of the FVC and FEV_1 and the FEV_1/FVC ratio were calculated in each exposure group. The mean values of both the FVC% and the FEV_1% decreased with increasing exposure, although the differences were not statistically significant. The mean values in all exposure groups were within the normal range.

TABLE 3. Exposure and smoking characteristics of high, medium, and low polyacrylate exposure groups

EXPOSURE GROUPS			
Relative Weighted Exposure (EWF x yrs)	High > 250	Medium 250 - 100	Low < 100
Total Cohort (164)	46 (28%)	54 (33%)	64 (39%)
Age*	53.2 yrs	53.9 yrs	48.2 yrs
Weighted exposure	516.0 RWE	151.9 RWE	44.1 RWE
Exposure years	16.2 yrs	10.6 yrs	6.3 yrs
Current smokers*	16 (35%)	14 (26%)	13 (20%)
Former smokers	18 (39%)	25 (46%)	22 (34%)
Never smokers	12 (26%)	15 (28%)	29 (45%)

*age, smoking not significant

TABLE 4. Mean percent of predicted values for FVC, FEV_1, and Ratio for high, medium and low polyacrylate exposure groups

LUNG FUNCTION			
Exposure	High (46)	Medium (54)	Low (64)
Average test year	1992 (83-95)	1992 (83-95)	1993 (85 - 95)
Average FVC%*	93.0%	97.6%	99.2%
Average FEV_1%*	90.0%	93.7%	96.1%
Average FEV_1/FVC	77.3%	76.4%	77.6%

*trend in averages not significant, t-distribution

As shown in **Table 5**, when lung function tests were classified as normal/abnormal (combining obstructive and restrictive), there appeared to be an excess risk of abnormal lung function in the

high and medium exposure groups when compared to the low exposure group. When the high and medium groups were combined the difference was statistically significant.

TABLE 5. Prevalence of normal and abnormal lung function results in high, medium, and low polyacrylate exposure groups

LUNG FUNCTION CATEGORY				
Exposure		**High (46)**	**Medium (54)**	**Low (64)**
Lung Function	**Normal**	**29 (63%)**	**35 (65%)**	**55 (86%)**
	Abnormal	**17 (37%)***	**19 (35%)***	**9 (14%)**

* Combined High/Medium v. Low, $X^2 = 10.3$, $p < .005$

When broken down by the pattern of lung function abnormality (**Table 6**), the high exposure group had an excess of individuals showing a restrictive pattern while the medium exposure group had an excess of persons showing an obstructive pattern. The obstructive lung function category was also associated with smoking status. When controlling for smoking, however, both excesses remained significant.

TABLE 6. Prevalence of normal, obstructive, and restrictive lung function tests in high, medium and low polyacrylate exposure groups

LUNG FUNCTION CATEGORY			
Exposure	**High (46)**	**Medium (54)**	**Low (64)**
Normal	**29 (63%)**	**35 (65%)**	**55 (86%)**
Obstructive	**7 (15%)**	**15 (28%)****	**7 (11%)**
Restrictive	**10 (22%)***	**4 (7%)**	**2 (3%)**

* chi square $p < .01$ for restrictive in high

** chi square $p < .05$ for obstructive in medium

To assess the impact of weighted exposure on lung function category, the mean weighted exposures were calculated for each category (**Table 7**). The mean weighted exposure for individuals with a restrictive pattern in lung function was significantly higher than for those with normal lung function. The mean weighted exposures for individuals with an obstructive pattern fell in between the restrictive and normal groups.

TABLE 7. Mean values of relative weighted exposures (RWF) for all polyacrylate exposure groups divided by workers with normal, obstructive and restrictive lung function tests

RELATIVE WEIGHTED EXPOSURE	
Lung Function Test	**Mean Relative Weighted Exposure (RWE)**
Normal	**179.8 (n = 119)**
Obstructive	**239.3 (n = 29)**
Restrictive	**409.1 * (n = 16)**

* anova High v. Low $p < .001$

In contrast, chest x-rays abnormalities were not associated with exposure. As shown in **Table 8,** there was a higher prevalence of x-ray abnormalities in the low exposure group. There was also no relationship between the x-ray findings and smoking or lung function testing.

TABLE 8. Chest x-ray results for high, medium and low polyacrylate exposure groups

CHEST X-RAYS			
Exposure	**High (46)**	**Medium (54)**	**Low (64)**
Normal	**39 (85%)**	**46 (85%)**	**56 (88%)**
Abnormal	**1 (2%)**	**3 (6%)**	**6 (11%)**
Not available	**6 (13%)**	**5 (9%)**	**2 (4%)**

not significant

Discussion

These findings suggest a possible relationship between exposure to polyacrylate dust and abnormalities in lung function. Comparisons using an exposure weighting factor and years worked suggest that long term workers with higher exposures are at risk for a loss of lung capacity in a restrictive pattern. These losses are not accompanied, however, by evidence of abnormalities on chest x-rays. In contrast, workers in the medium exposure category showed an obstructive pattern, more typical of that caused by smoking or exposure to irritants.

There are several limitations to this evaluation. The lung function data used was collected as part of the routine medical program at the facility. This was obtained in computer format and no attempt was made to confirm results through individual test and chart review. While most persons had relatively recent lung function testing, some individuals results dated back to the mid-1980's. Consistency should have been reasonable, however, since most of the tests analyzed were conducted by the facility nurse using a Puritan Bennett 900 spirometer purchased in 1987.

This was also a cross-sectional assessment of the last available lung function test. Due to variable availability and quality of testing prior to 1983, no attempt was made to obtain all lung function testing an each participant or to evaluate pre-exposure status. In addition, there was no medical history or questionnaire data obtained as a part of this evaluation. Other than smoking histories, there was no information available on personal health risks or exposures which could affect lung function. In addition, this did not include detailed exposure assessment of other materials at the facility, such as chlorine, acrylic acid, and asbestos. The finding of chest x-ray abnormalities in the population suggests that other exposures may be present which could have an effect on the lungs.

Despite the limitations of this survey and the fact that no lung cancers or chest -ray abnormalities were observed, these results warrant further attention. A number of polyacrylate materials exhibit a range of toxicologic effects in the respiratory system. Furthermore, some polyacrylates appear to have protracted clearance form the lung[2,6]. The finding of a restrictive pattern in the high exposure group and an obstructive pattern in the medium group could indicate that at lower exposures pulmonary defense mechanisms are actively involved in clearing inhaled dust from the lungs. With longer term or higher exposures, clearance mechanisms may be exceeded, leading to pulmonary accumulation. The lack of x-ray findings suggests that the reduction in lung capacity may be related to delayed clearance, rather than pulmonary fibrosis. This could possibly be reversible over time.

In conclusion, a respiratory survey of workers exposed to polyacrylate dust suggests that long-term high level inhalation of respirable dust may have respiratory effects. While there was no evidence of an excess risk of lung cancer or chest x-ray abnormalities, there were exposure related decrements in lung function. This was intended to be a cross-sectional preliminary assessment and as a result there are several limitations in both the medical and exposure data analyzed. Given both these findings and the results of animal studies, however, efforts at the facility to minimize respiratory exposure to this material should continue.

REFERENCES

1 Toxic Substances Control Act, Section 8(e) submission 8EHQ-0382-0438S, February 23, 1982.

2 West, AS: Toxic Substances Control Act, Section 8(e) submission by Rohm and Haas, Results of 90 day inhalation study of polyacrylate product. August 15, 1985.

3 Institute for Polyacrylate Absorbents, Inc. Toxic Substances Control Act, Section 8(e) submission of final results of a two year rat inhalation study with micronized polyacrylate dust, June 27, 1994.

4 BFGoodrich unpublished occupational health survey of employees at Calvert City, Kentucky involved in the manufacture of polyacrylate products, 1983.

5 Voit, JE: Rohm and Haas customer communication, July 19, 1984

6 Institute for Polyacrylate Absorbents, Inc. unpublished polyacrylate dust deposition and fate study, 1995.